Claims

1. An assay to simultaneously detect the presence of antigen and antibody analytes of a human immunedeficiency virus (HIV) in a sample, comprising the steps of
simultaneously or sequentially contacting the sample with
a) at least one antigen capture reagent which is an antibody or a fragment thereof specific for an epitope on a gag antigen analyte,
b) at least two antibody capture reagents wherein
one antibody capture reagent comprises an epitope which is specific for an envelope antibody analyte, and
one antibody capture reagent comprises an epitope which is specific for a capsid antibody analyte, and
c) detecting the antigen/antigen capture reagent and antibody/antibody capture reagent complexes,
provided that the gag antigen analyte is not the capsid antigen.

2. The assay according to claim 1, wherein the antigen analytes and the antibody analytes are detected by contacting the analytes with
a) at least one antigen indicator reagent which is an antibody or a fragment thereof specific for an epitope in the gag antigen analyte, and
b) with at least two antibody indicator reagents wherein
one antibody indicator reagent comprises an epitope which is specific for the envelope antibody analyte, and
one antibody indicator reagent comprises an epitope which is specific for the capsid antibody analyte,
and wherein each of the antibody indicator reagents has the same epitope specificity as the corresponding antibody capture reagent.

3. The assay according to claim 1 or claim 2, wherein the antigen analytes and the antibody analytes belong to a virus from the group of HIV-1, HIV-2 or HIV-3.

4. The assay according to any one of claims 1-3, wherein one gag antigen analyte is detected and one antibody analyte for an envelope antigen and one antibody analyte for the capsid antigen are detected.

5. The assay according to any one of claims 1-4, wherein the capture reagent for the capsid antibody analyte crossreacts with an antibody analyte for the capsid antigen of another HIV.

6. The assay according to any one of claims 1-5, wherein additional antigen and/or antibody capture reagents specific for a gag antigen or envelope antibody analyte of another HIV are added.

7. The assay according to any one of claims claim 1-6, wherein the antibody analyte specific for the envelope antigen is a low affinity antibody, and
the antibody analyte specific for the capsid antigen is a high affinity antibody.

8. The assay according to claim 7, wherein the low affinity antibody is IgM and the high affinity antibody is IgG, IgA and/or IgE.

9. The assay according to any one of claims 1-6, wherein the antigen capture reagents and the antibody capture reagents are bound or can be bound to the same support or to different supports.

10. The assay according to claim 9, wherein
a) one antigen capture reagent is bound or can be bound to a first support and
b) the two antibody capture reagents specific for the envelope and the capsid antibody analytes are bound or can be bound independently either alone or in any combination to the first and/or to a second support or to a second and/or a third support.

11. The assay according to claim 9 or claim 10, wherein
a) the antibody capture reagent specific for the envelope antibody analyte is bound to a support or can be bound to a support in a density for binding and detecting a low affinity antibody, and
b) the antibody capture reagent for the capsid antibody analyte is bound to a support or can be bound to a support in a density for binding and detecting a high affinity antibody.

12. The assay according to claim 1, wherein the virus is from the group of HIV-1 and
a) one antigen capture reagent is an antibody or a fragment thereof which is specific for an epitope on the HIV-1 gag proteins p17, p2, p7, p1, or p6,
b) one antibody capture reagent for the envelope antibody analyte comprises an epitope which is specific for the HIV-1 envelope gp160 or gp41 protein, and

one antibody capture reagent for the capsid antibody analyte comprises an epitope which is specific for the HIV-1 p24 protein.

13. The assay according to claim 12, wherein the antibody capture reagent for the envelope antibody analyte is a peptide or polypeptide comprising the aminoacid sequence CSGKLIC or CSGKIIC from gp41 or a variant thereof in its S-S cyclic or non cyclic form or as a mixture of cyclic and non cyclic form.

14. The assay according to claim 12 or claim 13, wherein the antigen capture reagent is an antibody or a fragment thereof specific for an epitope on the p17 or p7 protein,

15. The assay according to claim 6, wherein the assay comprises the steps of simultaneously or sequentially contacting the sample with
a) at least one antigen capture reagent which is an antibody or a fragment thereof specific for an epitope on an HIV-1 gag antigen and/or one antigen capture reagent which is an antibody or a fragment thereof specific for an epitope on an HIV-2 gag antigen analyte,
b) two antibody capture reagents wherein
one antibody capture reagent comprises an epitope which is specific for an HIV-1 envelope antibody analyte,
one antibody capture reagent comprises an epitope which is specific for an HIV-1 capsid antibody analyte, and
c) one antibody capture reagent comprises an epitope which is specific for an HIV-2 envelope antibody analyte, and
d) detecting the antigen/antigen capture reagent and antibody/antibody capture reagent complexes,
provided that the gag antigen analyte is not the capsid antigen.

16. The assay according to claim 15, wherein the antibody capture reagent specific for an HIV-1 capsid antibody analyte crossreacts with an HIV-2 capsid antibody analyte.

17. The assay according to claim 15 or claim 16, wherein an antibody capture reagent is added which comprises an epitope which is specific for an HIV-3 envelope antibody analyte.

18. The assay according to any one of claims 12-17, wherein
a) the antigen analyte is detected by an antigen indicator reagent which is an antibody or a fragment thereof specific for an epitope on the gag antigen, and

b) each of the antibody analytes is detected with an antibody indicator reagent having the same epitope specificity as the corresponding antibody capture reagent.

19. A test kit to simultaneously detect the presence of at least one HIV antigen analyte and at least two antibody analytes of an HIV in a sample comprising
a) at least one antigen capture reagent which is an antibody or a fragment thereof specific for an epitope in a gag antigen analyte, and
b) at least two antibody capture reagents wherein
one antibody capture reagent comprises an epitope which is specific for an envelope antibody analyte and
one antibody capture reagent comprises an epitope which is specific for a capsid antibody analyte,
provided that the gag antigen analyte is not the capsid antigen.

20. The test kit according to claim 19, which further comprises
a) at least one antigen indicator reagent specific for an epitope on the gag antigen analyte which indicator reagent is labelled or can be labelled, and
b) at least two antibody indicator reagents for the envelope and capsid antibody analytes which reagents have the same epitope specificity as the corresponding antibody capture reagents and which are labelled or can be labelled.

21. The test kit according to claim 18 or claim 20 for detecting antigen and antibody analytes of an HIV-1, comprising
a) an antigen capture reagent which is an antibody or a fragment thereof specific for an epitope on the HIV-1 gag proteins p17 or p7
b) an antibody capture reagent specific for the envelope antibody analyte which reagent is a polypeptide comprising the aminoacid sequence CSGKLIC or CSGKIIC from gp41 HIV-1 or any other variant thereof in its S-S cyclic or non cyclic form or as a mixture of cyclic and non cyclic form and an antibody capture reagent for the capsid antibody analyte which reagent is a polypeptide comprising an epitope which is specific for the HIV-1 p24 protein.

22. The test kit according to claim 21, which further comprises
a) an antigen indicator reagent which is an antibody or a fragment thereof specific for an epitope in one of the HIV-1 gag proteins p17 or p7, and
b) antibody indicator reagents for each of the gp41 envelope and p24 antibody

analytes having the same epitope specificity as the corresponding antibody capture reagents,
wherein all indicator reagents are labelled or can be labelled.

23. The test kit according to claim 22, wherein
a) the antigen capture and indicator reagents are a pair of anti-p7 antibodies or fragments thereof,
b) the capture and indicator reagent for the envelope antibody analyte is recombinant gp41, and
the capture and indicator reagent for the capsid antibody analyte is recombinant p24,
wherein all indicator reagents are labelled or can be labelled.

24. The test kit according to any one of claims 21-23, which further comprises
c) an antibody capture reagent specific for an HIV-2 envelope antibody analyte which reagent is a polypeptide comprising the aminoacid sequence CAFRQVC from gp36 HIV-2 or any other variant thereof in its S-S cyclic or non cyclic form or as a mixture of cyclic and non cyclic form and/or
d) an antibody capture reagent specific for an HIV-3 envelope antibody analyte which reagent is a polypeptide comprising the aminoacid sequence CKGKLVC from gp41 HIV-3 or any other variant thereof in its S-S cyclic or non cyclic form or as a mixture of cyclic and non cyclic form, and
e) antibody indicator reagents having the same epitope specificity for the envelope antibody analytes as the antibody capture reagents which indicator reagents are labelled or can be labelled.

25. The test kit according to any one of claims 21-24, which further comprises means for labeling and/or detecting the indicator reagents.

26. Use of a test kit according to any one of claims 19-25 for the detection of HIV antigen and antibody analytes in a sample.

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